

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

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The ISBT 128s Are Coming

by Linda Parisi, DOH/LQA

Blood donor centers (DC) in the United States are in the process of implementing International Society of Blood Transfusion (ISBT) 128 labels and most centers have started communication with transfusion services. The ISBT 128 labels are an informational standard for identifying, labeling, and processing of human blood, tissue, and organ products across international borders. During the past 20 years, technology has expanded and the current labeling system (Codebar) has reached the limit of its ability to communicate critical information. The complexity of manipulations that can be made to blood components requires a more robust system for labeling products. The ability to electronically verify appropriate labeling of blood products provides tremendous value in support of patient safety.

Implementation of ISBT 128 labels is not mandated by the FDA, but it does require that specific information on any blood component be "machine readable" by April 24, 2006. The elements that must be machine readable, according to the final rule "Bar Code Label Requirement for Human Drug Products and Biological Products" published in the Federal Register (February 26, 2004), are the donation identification number, ABO/Rh, the product code, and the unique facility identifier. The ISBT 128 symbology allows a unit to be identified around the world without relying on eye-readable information in a different language. The assignment of a unique facility identification code and the maintenance of the product database is coordinated by ICCBBA (formerly known as the International Council for Commonality in Blood Bank Automation).

Transition to the ISBT 128 labels will require coordination with areas outside the laboratory as well as other departments within the laboratory. As an example, the microbiology department may be involved in evaluation of transfusion reactions requiring documentation of the donation identification number and component. Anyone involved in recording a donation identification number must become familiar with the changes in the blood bag label. Facilities using electronic scanners or interfaces with laboratory equipment will need to evaluate their ability to read and appropriately transmit the information. Facilities relying on manual documentation and manual computer downtime forms will need to evaluate current documents and forms to make sure that there is adequate space to record the new 13-character identification number. The development of a cross-functional team with representatives from nursing, anesthesiology, information systems,

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/lqa.htm

Anemia	Lipid Screening
ANA	PAP Smear
Bioterrorism Event Mgmt	Point-of-Care Testing
Bleeding Disorders	PSA
Chlamydia	Rash Illness
Diabetes	Red Cell Transfusion
Group A Strep Pharyngitis	Renal Disease
Group B Streptococcus	STD
Hepatitis	Thyroid
HIV	Tuberculosis
Infectious Diarrhea	Urinalysis
Intestinal Parasites	Wellness

Tips for Quality Waived Test Performance

by Kathy LaBeau, DOH/LQA

This article begins a series of tips for performing quality waived testing in your laboratory. A series of articles will appear in the next several issues of the *Elaborations* newsletter.

Waived tests are generally easy to perform, but that is not to say that problems do not occur if you do not perform the test properly, read the manufacturer's package insert, or follow good laboratory practices when testing patient samples. These tips are designed to assist you in providing quality test results for your patients.

Good Practices when Performing Waived Testing

- Make sure your test kit is CLIA-waived. Sometimes distributors inadvertently substitute kits that are moderate-complexity when your regular waived product is unavailable. The test complexity is usually marked on the outside of the test kit or in the product insert.
- Make sure that your product insert is current and there are no changes by the manufacturer. Changes are usually clearly marked on the test kit or in the product insert to alert you.
- Follow the steps in the test procedure exactly as

described - no short cuts or modifications.

- Do not interchange reagents with other kits or lots.
- Do not interchange caps of reagents.
- Do not use expired reagents or kits.
- Adhere strictly to the timing of the addition of reagents and of the final readout of results. Incorrect timing can give erroneous results. Have a system in place to remind you of the correct time frame, such as the use of a timer.
- Test controls as required by the manufacturer.
- If controls (external, internal, electronic) fail to give the expected results, do not report patient results until the problem is resolved.
- Use common sense. If patient results do not agree with clinical expectations (e.g., all patient Strep tests are negative during the peak season), discuss with your director and investigate with the test manufacturer.

Considerations for Waived Test Specimens

- Waived tests are approved for use only with direct, unprocessed specimens that do not require operator manipulation. Specimens that require centrifugation, dilution, extraction or other preparation steps are not appropriate for waived tests.
- Be sure that blood samples are collected in the correct anticoagulant (if applicable).
- If samples are not tested immediately, they should be held under conditions specified in the manufacturer's instructions (e.g., specimens for urinalysis should be refrigerated if not tested right away).
- For specimens collected on a swab (e.g., Strep antigen testing), assure that the correct type of swab is used for your test system. For some test kits, swabs with wooden shafts and cotton tips are unacceptable.
- A single product insert might include instructions for performing a waived test using whole blood and for performing the same test using plasma or serum, which would not be waived. A test for hCG (pregnancy test) may be considered waived if using urine, but not waived if performed on serum or plasma.

Other topics in this series that will appear in future issues of *Elaborations* include Considerations when Adding New Waived Tests, Getting Prepared to Perform Waived Testing, and Quality Control and Waived Tests.

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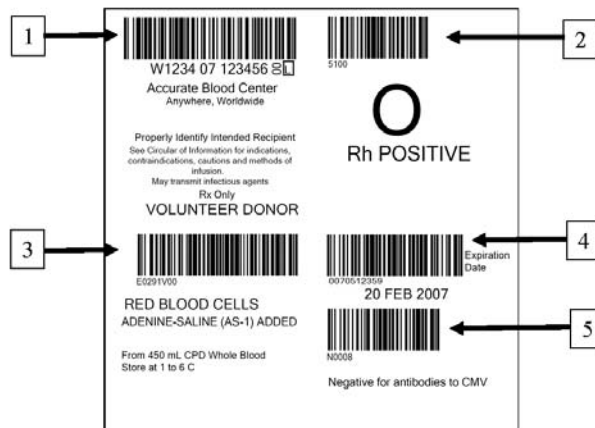
Website addresses:

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LQA home page: <http://www.doh.wa.gov/lqa.htm>
PHL home page:
<http://www.doh.wa.gov/EHSPHL/PHL/default.htm>

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billing, and medical records may be indicated. They will need to evaluate and revise forms and computer or electronic records to ensure that the 13-character donation identification number can be read, transmitted, printed, and retained correctly.

ISBT 128-specified label



- 1 = Donation Identification Number
- 2 = ABO/RH Blood Groups
- 3 = Product Code
- 4 = Expiration Date and Time
- 5 = Special Testing

The best way to assess the operational impact of ISBT 128 labels implementation in your facility is to develop a plan that identifies the scope of services provided by the facility. The plan will identify whether the facility needs to register with ICCBBA. Registration with ICCBBA is different from registration with the FDA, and the criteria defining who must register are not the same. As an example, facilities that only pool or aliquot blood components do not register with the FDA, but they must register with ICCBBA because the label applied to the final component will need to include ISBT data structures.

Each transfusion service will have its own unique implementation plan, but all plans will involve the direct coordination of efforts beyond the laboratory for success. Communication and training will be the most important points to be addressed in the implementation plan.

Adapted with permission from Marianne A. Silva from "ISBT 128: Beyond the Label" LabMedicine, Volume 38, November 4, April 2007.

Tips for Quality Waived Test Performance

This issue begins a series of tips for performing quality waived testing in your laboratory. A series of articles will appear in the next several issues of the *Elaborations* newsletter.

See page 2 for the first installment in this series.

Calendar of Events

PHL Training Classes:
(<http://www.doh.wa.gov/ehsphi/phl/training/train.htm>)

Basic Microscopy

August 8 OR 9 Shoreline

Northwest Medical Laboratory Symposium

October 24-27 Seattle

14th Annual Clinical Laboratory Conference

November 12 Seattle

2008 WSSCLS/NWSSAMT Spring Meeting

April 24-26, 2008 Lynnwood

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.